PATENT
Customer No. 22,852
Attorney Docket No. **2481.1699-00**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Henning VOLLERT

Application No.: 09/646,986

Filed: September 26, 2000

For: MINIATURIZED MICROTITER PLATE FOR HIGH THROUGHPUT SCREENING

Group Art Unit: 1743

Examiner: D. Handy

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPEAL BRIEF UNDER 37 C.F.R. § 1.192

Appellant's Appeal Brief in connection with the above-captioned patent application is hereby submitted in triplicate. A Notice of Appeal was timely filed on July 25, 2003, in response to the final Office Action of January 28, 2003. The period for filing the Appeal Brief has been extended two months to November 25, 2003 by the petition and fee filed herewith. Each item required by 37 C.F.R. § 1.192 is set forth below.

I. Real Party In Interest

The real party in interest is Aventis Pharma Deutschland GmbH, located at Brüningstrasse 50, D-65929 Frankfurt am Main, Germany.

II. Related Appeals and Interferences

On information and belief, there are no related Appeals or Interferences.

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III. Status Of Claims

Claims 1-4 have been canceled. Claims 5-13 are currently pending in this application. Claims 5-13 are the subject of this appeal. A clean copy of claims 5-13 is found in the Appendix.

IV. Status Of Amendments

Appellant filed an Amendment After Final on July 25, 2003, and this amendment will be entered upon the filing of this Appeal Brief per the Advisory Action dated August 21, 2003.

V. Summary Of Invention

The present invention, as defined by independent claim 5, is directed to a miniaturized microtiter plate for high throughput screening. The miniaturized microtiter plate includes a plastic body, a glass base, and a lid to prevent evaporation. The base of the microtiter plate has a thickness ranging from 0.07 to 0.2 mm. The microtiter plates also has 1000 to 4000 vessels for containing samples, the diameter of the vessels ranging from 1.0 to 1.8 mm. The distance between the center of the outer vessels and an edge of the glass base ranges from 4 to 11 mm. (Claim 1; page 2, lines 1-10).

The present invention, as defined by claim 6, may also be directed to a miniaturized microtiter plate wherein the number of vessels ranges from 1400 to 2500, the diameter of the vessels ranges from 1.2 to 1.5 mm, and the thickness of the base ranges from 0.12 to 0.17 mm. (Claim 2; page 2, lines 1-10). The present invention, as defined by each of claims 7 and 8, may also be directed to a miniaturized microtiter plate including 1536 vessels. (Claim 3; page 2, lines 1-10).

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The present invention, as defined by each of claims 9, 10, and 11, may also be directed to a miniaturized microtiter plate wherein the thickness of the base is 0.15 mm. (Claim 4; page 2, lines 1-10). The present invention, as defined by claim 12, may also be directed to a miniaturized microtiter plate wherein the base is coated with a substance to suppress nonspecific binding. (Page 3, lines 8-11). The present invention, as defined by claim 13, may also be directed to a miniaturized microtiter plate wherein the base is coated with a substance to encourage specific binding. (Page 3, lines 11-14).

Prior art microtiter plates do not allow analysis using confocal optics. (Page 1, lines 33-34). In the present invention, the thickness of the glass base (0.07-0.20 mm), the diameter of the vessels (1.0-1.8 mm), and the distance between the center of the outer vessels and the edge of the glass base (4-11 mm) allow analysis of the microtiter plate of the present invention using confocal optics. The use of confocal optics has several advantages. For example, the sensitivity of confocal optics is higher than non-confocal optics, as even individual molecules can be detected in some circumstances. Because the sensitivity is higher, the measurement time can be reduced, and thus the overall analysis rate of a microtiter plate can be increased. In another example, since the focus of confocal optics is very small, detection of background noise is greatly reduced, thus improving the signal/noise ratio. (Page 2, line 30 through page 3, line 6).

VI. Issues

There is one issue on appeal, as set forth below:

> Whether claims 5-13 recite patentable subject matter under 35 U.S.C. § 102(b) in view of Pham et al., U.S. Patent No. 6,171,780 B1.

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VII. Grouping Of Claims

Claims 5-13 stand or fall together.

VIII. Argument

Claims 5-13 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Pham et al., U.S. Patent No. 6,171,780 B1. Page 2 of the Final Rejection (Paper No. 8).

A. Law on Anticipation Under 35 U.S.C. § 102(b):

35 U.S.C. § 102(b) states:

> A person shall be entitled to a patent unless the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than a year prior to the date of application for patent in the United States.

Accordingly, a person is not entitled to a patent if the claimed invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than a year prior to the filing date of the U.S. patent application. A claim is anticipated, however, only if each and every element set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053, (Fed. Cir. 1987). Further, an anticipating prior art patent or printed publication must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention. See In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990); Diversitech Corp. v. Century Steps, Inc., 850 F.2d 1566, 1567, 7 USPQ2d 1315, 1317 (Fed. Cir. 1988).

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The rejection of claims 5-13 under 35 U.S.C. § 102(b) should be withdrawn. Pham et al. does not disclose, either expressly or inherently, the specific combination of elements within narrowly defined ranges that are recited in the claims. Claim 5 recites a combination including a plastic body, a glass base, the base of the microtiter plate having a thickness ranging from 0.07 to 0.2 mm, a number of vessels for containing samples, wherein the number of vessels ranges from 1000 to 4000 vessels, the diameter of the vessels ranges from 1.0 to 1.8 mm, and the distance between the center of the outer vessels and an edge of the glass base ranges from 4 to 11 mm, and a lid to prevent evaporation.

Moreover, Pham et al. does not disclose, either expressly or inherently, each and every element set forth in the claims, nor does it describe the claimed invention in sufficient clarity and detail. For example, claim 5 requires that at least the following feature of the claimed microtiter plate be present:

the distance between the center of the outer vessels and an edge of the glass base ranges from 4 to 11 mm.

This feature is not described in Pham et al.

In rejecting claims 5-13, the Examiner asserted that Pham et al. discloses the invention as claimed. The Examiner asserted that Pham et al. discloses a low fluorescence platform that contains a large number of wells for assaying compounds. The Examiner stated that the platform may contain between 50 and 10,000 wells, that the frame may be made of "any material, such as polymers, such as polystyrene or cycloolefins, or other materials such as glass or quartz." The Examiner further stated that the base may be made of glass, and that the frame and base may be made of the

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same or different materials. With regard to the wells, the Examiner stated that the wells may have a diameter of between 0.2 and 50 mm, and a thickness for the base of between 10-1000 micrometers. Page 3 of the Non-Final Rejection dated June 19, 2002.

Finally, the Examiner stated that one limitation of the distance between the center of the outer vessels and an edge of the glass base of between 4 and 11 mm as claimed by Applicant is inherent to Pham et al. Page 3 of the Final Rejection (Paper No. 8).

B. Pham et al. Does Not Disclose the Claimed Ranges With Specificity

"In order to anticipate the claims, the claimed subjected matter must be disclosed in the reference with 'sufficient specificity to constitute anticipation under the statute." See M.P.E.P. §2131.03. Furthermore, "[i]f the claims are directed to a narrow range, the reference teaches a broad range, and there is evidence of unexpected results within the claimed narrow range, depending on the facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with 'sufficient specificity' to constitute an anticipation of the claims." Id. The instant case falls into such a category, as the claims of the present application include elements defined by specific ranges, while Pham et al. teaches broad ranges, often without specific examples falling within the claimed range. And the specific claimed ranges of the invention result in a microtiter plate that allows confocal optical analysis.

For example, claim 5 recites that the base of the microtiter plate has a thickness ranging from 0.07 to 0.2 mm. Pham et al. teaches a base thickness of 10-1000

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micrometers (.010-1.0 mm) in column 13, lines 60-68, with a most preferred range being between 20 and 100 micrometers (.020 and 0.1 mm).

In another example, claim 5 recites that the diameter of the vessels ranges from 1.0 to 1.8 mm. Pham et al. teaches a vessel diameter of between 0.2 and 100 mm, with a most preferred range being between 2 and 20 mm. See column 13, lines 3-10. These ranges are completely outside the claimed range.

In a further example, claim 5 recites that the distance between the center of the outer vessels and an edge of the glass base ranges from 4 to 11 mm. Pham et al. is completely silent with regard to this measurement. The Examiner acknowledged that Pham et al. does not disclose this element, but argued that it is inherent. However, as set forth below, this element is not inherently disclosed by Pham et al.

Moreover, Applicant asserts that the specific ranges are important because the specific combination of elements within the claimed ranges permits the resulting microtiter plate to be used with confocal optics, a sensitive method of detection for which Pham et al.'s teaching is silent and Pham et al.'s device as disclosed is unsuitable. Accordingly, Applicant asserts that the specific ranges claimed in this application are not disclosed with "sufficient specificity" in Pham et al. to constitute an anticipation of claims 5-13. Id. Reconsideration is requested.

Additionally, for Pham et al. to anticipate the claimed invention, Pham et al. must clearly and unequivocally disclose the claimed combination of elements within their specific claimed ranges or direct those skilled in the art to the specific claimed ranges "without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference." See In re Arkley, 455

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F.2d 586, 587 (C.C.P.A. 1972). "Unless all of the same elements are found in exactly the same situation and united in the same way to perform the identical function in a single prior art reference, there is no anticipation." General Battery Corp. v. Gould, 545 F. Supp. 731, 744 (D. Del. 1982). Such is the case here. Indeed, the Examiner has chosen arbitrary numbers from broad ranges and from unrelated portions of the reference in an attempt to anticipate the claimed invention. Such an attempt does not meet the requirements of In re Arkley. Furthermore, Pham et al. does not disclose the microtiter plate, even in the configuration alleged by the Examiner, performing the identical function as the claimed invention as required by General Battery Corp. v. Gould. Accordingly, Pham et al. does not anticipate the claimed invention as set forth in claims 5-13.

C) The Distance of Between 4 and 11 mm is Not Inherent in Pham et al.

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is **necessarily** present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing **may** result from a given set of circumstances is not sufficient." In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added). See also M.P.E.P. §2112.

In the present case, the Examiner has **not** established that a microtiter plate made in accordance with the disclosure of Pham et al. **necessarily** has a distance between the center of the outer vessels and an edge of the glass base between 4 and 11 mm, as recited in claim 5. Indeed, Pham et al. discloses a wide range of values for a

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broad range of characteristics that Appellant submits will result in tens of thousands of permutations of a microtiter plate that one of ordinary skill **may** create from the broad teachings of Pham et al. Among the tens of thousands of permutations, some of these microtiter plates **may arguendo** include a distance between the center of the outer vessels and an edge of the glass base of between 4 and 11 mm, however, the vast majority will **not**. Therefore, a distance between the center of the outer vessels and an edge of the glass base of between 4 and 11 mm does not **necessarily** flow from the teachings of Pham et al. as required by In re Robertson. Because Pham et al. does not **necessarily** disclose that the distance between the center of the outer vessels and an edge of the glass base in a microtiter plate is between 4 and 11 mm, Pham et al. does not inherently disclose Appellant's claim 5.

Moreover, Appellant asserts that the Examiner erred in calculating the alleged distance between the center of the outer vessels and an edge of the base in Pham et al. (Paper No. 8, pages 3-4). This further supports Appellant's position that Pham et al. does not inherently disclose the invention recited in claim 5. Specifically, the Examiner allegedly calculated the distance between the center of the outer vessels and an edge of the base based on dimensions found in Table I of Pham et al. and in columns 11 and 12 of Pham et al. The Examiner assumed that a multi-well platform has an 85.5 mm by 127.75 mm base, and asserted that these base dimensions were taken from Table I of Pham et al. However, Pham et al. and Table I do not disclose such **base** dimensions, but rather disclose a **frame or footprint** dimension (see column 10, lines 15-16 and lines 34-36). Claim 5 recites in relevant part, "distance between the center of the outer vessels and an **edge of the glass base**," emphasis added. As shown in Figs. 2 and 3

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of the present application, it is the frame 1, and not the glass base 2, which defines the footprint of the plate. Because Pham et al. does not discuss or show the construction of the entire device, it is unclear whether the base of Pham et al. extends to the edge of the frame, and thus has the same dimensions as the frame. Pham et al. does state that the base and frame may or may not be integrally formed (col. 15, lines 44-50), however, Pham et al. gives no guidance as to where the base ends and the frame begins. Thus, with measurements provided **only for the frame or footprint** of the microtiter plate, and not for the **base**, one cannot determine the distance between the center of the outer vessels and an edge of the base in Pham et al.. Thus, Pham et al. does not disclose or inherently suggest a distance between the center of the outer vessels and an edge of the glass base being between 4 and 11 mm.

Further, Table I of Pham et al., from which the Examiner took the alleged base dimensions, discloses the maximum number of vessels as being 384. To increase the number of vessels, as set forth by the Examiner, to 1536 (arbitrarily chosen from a disclosed range of 50 to 10,000 (column 11, lines 44-59)) would markedly increase the alleged base dimensions, with no guidance in Pham et al. as to what distance between the center of the outer vessels and an edge of the base would result. In contrast, to markedly decrease the well center-to-well center spacing, as set forth by the Examiner, to 0.5 mm (arbitrarily chosen from a disclosed range of 0.5 mm to 100 mm (column 12, lines 53-55)) would markedly decrease the area covered by the wells, and again there is no guidance in Pham et al. as to what distance between the center of the outer vessels and an edge of the base would result. Accordingly, because the Examiner changed various parameters in Table I rather than using a specific example from Pham et al., it is

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clear that the Examiner has impermissibly picked and chosen among the disparate disclosures of Pham et al. so as to support this rejection. Therefore, the Examiner has not established that Pham et al. **necessarily** discloses that the distance between the center of the outer vessels and an edge of the glass base is between 4 and 11 mm, and therefore, for this reason also, inherency is not proven.

Favorable consideration of claims 5-13 and reversal of this rejection is respectfully requested.

Conclusion

In conclusion, Appellant submits that the rejections of claims 5-13 should be reversed. Pham et al. does not disclose or suggest a microtiter plate with the claimed features. Further, there is no motivation to provide a microtiter plate with the claimed features because it would require one of ordinary skill in the art to arbitrarily choose and combine various discrete features across broad ranges of disparate portions of Pham et al. This could not be done without using the claimed invention as a template. Therefore, Pham et al. does not anticipate claim 5 or any claim that depends therefrom.

To the extent any further extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 06-0916.

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Respectfully submitted,

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Dated: November 12, 2003

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Appendix of the Claims Appealed

5. A miniaturized microtiter plate comprising:

a plastic body;

a glass base, the base of the microtiter plate having a thickness ranging from 0.07 to 0.2 mm;

a number of vessels for containing samples, wherein the number of vessels ranges from 1000 to 4000 vessels, the diameter of the vessels ranges from 1.0 to 1.8 mm, and the distance between the center of the outer vessels and an edge of the glass base ranges from 4 to 11 mm; and

a lid to prevent evaporation.

6. The miniaturized microtiter plate of claim 5, wherein the number of vessels ranges from 1400 to 2500, the diameter of the vessels ranges from 1.2 to 1.5 mm, and the thickness of the base ranges from 0.12 to 0.17 mm.

7. The minaturized microtiter plate of claim 5, wherein there are 1536 vessels.

8. The minaturized microtiter plate of claim 6, wherein there are 1536 vessels.

9. The miniaturized microtiter plate of claim 5, wherein the thickness of the base is 0.15 mm.

10. The miniaturized microtiter plate of claim 6, wherein the thickness of the base is 0.15 mm.

11. The miniaturized microtiter plate of claim 8, wherein the thickness of the base is 0.15 mm.

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12. The miniaturized microtiter plate of claim 5, wherein the base is coated with a substance to suppress nonspecific binding.

13. The miniaturized microtiter plate of claim 5, wherein the base is coated with a substance to encourage specific binding.

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